(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(e) *Determination of equivalence or difference of requirements applicable to a device.* It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the Federal Food, Drug, and Cosmetic Act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) *Applicability of Federal requirements respecting devices.* The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

(g) *Exemptions not applicable to certain State or local government requirements specifically related to hearing products.* An exemption under this part shall not apply to any State or local government law, regulation, order, or other requirement specifically related to hearing products, including any requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids, that:

(1) Would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online; and

(2) Is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017.

[43 FR 18665, May 2, 1978, as amended at 45 FR 67336, Oct. 10, 1980; 61 FR 52654, Oct. 7, 1996; 73 FR 34859, June 19, 2008; 87 FR 50761, Aug. 17, 2022]

§ 808.3 Definitions.

Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.

Political subdivision or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

State means any State or Territory of the United States, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

[87 FR 50762, Aug. 17, 2022]

§ 808.5 Advisory opinions.

(a) Any State, political subdivision, or other interested person may request an advisory opinion from the Commissioner with respect to any general matter concerning preemption of State or local device requirements or with respect to whether the Food and Drug Administration regards particular State or local requirements, or proposed requirements, as preempted.